3763

Docket No.: BVTP-P04-506
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Allen et al.

Application No.: 10/010723

Group Art Unit: 3763

Filed: December 6, 2001

Examiner: Thompson, Kathryn L.

For: MICRONEEDLE DEVICES AND METHODS OF MANUFACTURE AND USE THEREOF

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
Washington, DC 20231

Pursuant to 37 CFR 1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed more than three months after the U.S. filing date, OR more than three months after the date of entry of the national stage of a PCT application, AND after the mailing date of the first Office Action on the merits, whichever occurs first, but before the mailing date of a Final Rejection or Notice of Allowance.

This is Part Two of a two-part Information Disclosure Statement. Part One, citing U.S. Patent art, was filed electronically on the above signed date. The fee of $180.00 set forth under 37 C.F.R. 1.17(p) was paid online with Part One.

Those patent(s) or publication(s) which are not marked with an asterisk (*) on the attached Form PTO/SB/08 are not supplied because they were previously cited by or submitted to the Office in prior application no. 09/316,229 filed 05/21/1999, now PAT 6,334,856 which is relied upon in this application for an earlier filing date under 35 U.S.C. 120.

While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents should one or more of the documents be applied against the claims of the present application.

The Commissioner is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. BVTP-P04-506.

Dated: 4/4/03

Respectfully submitted,

By _____

Agnes S. Lee
Registration No.: 46,862
ROPES & GRAY
One International Place
Boston, Massachusetts 02110-2624
(617) 951-7000
(617) 951-7050 (Fax)
Attorneys/Agents For Applicant

PTO/SB/08A (10-01)
Approved for use through 10/31/2002.OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	10/010723
Filing Date	December 6, 2001
First Named Inventor	Mark G. Allen
Art Unit	3763
Examiner Name	Thompson, Kathryn L.
Attorney Docket Number	BVTP-P04-506

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	2,893,392	07/07/1959	Wagner et al.	
	AB	3,034,507	05/15/1962	McConnell et al.	
	AC	3,086,530	04/23/1963	Groom	
	AD	3,123,212	03/03/1964	Taylor et al.	
	AE	3,136,314	06/09/1964	Kravitz	
	AF	RE 25,637	09/08/1964	Kravitz et al.	
	AG	3,221,739	12/07/1965	Rosenthal	
	AH	3,221,740	12/07/1965	Rosenthal	
	AI	3,556,080	01/19/1971	Hein	
	AJ	3,596,660	08/03/1971	Melone	
	AK	3,675,766	07/11/1972	Rosenthal	
	AL	3,918,449	11/11/1975	Pistor	
	AM	3,964,482	06/22/1976	Gerstel et al.	
	AN	4,109,655	08/29/1978	Chacornac	
	AO	4,159,659	07/03/1979	Nightingale	
	AP	4,222,392	09/16/1980	Brennan	
	AQ	4,771,660	09/20/1988	Yacowitz	
	AR	4,798,582	01/17/1989	Sarath et al.	
	AS	4,921,475	05/01/1990	Sibalis	
	AT	4,969,468	11/13/1990	Byers et al.	
	AU	5,054,339	10/08/1991	Yacowitz	
	AV	5,138,220	08/11/1992	Kirkpatrick	
	AW	5,250,023	10/05/1993	Lee et al.	
	AX	5,279,544	01/18/1994	Gross et al.	
	AY	5,279,552	01/18/1994	Magnet	
	AZ	5,335,670	08/09/1994	Fishman	
	BA	5,364,374	11/15/1994	Morrison et al.	
	BB	5,383,512	01/24/1995	Jarvis	
	BC	5,401,242	03/28/1995	Yacowitz	
	BD	5,457,041	10/10/1995	Ginaven et al.	
	BE	5,527,288	06/18/1996	Gross et al.	
	BF	5,582,184	12/10/1996	Erickson et al.	
	BG	5,591,139	01/07/1997	Lin et al.	
	BH	5,611,806	03/18/1997	Jang	
	BI	5,611,809	03/18/1997	Marshall et al.	
	BJ	5,618,295	04/08/1997	Min	
	BK	5,658,515	08/19/1997	Lee et al.	
	BL	5,697,901	12/16/1997	Eriksson	
	BM	5,801,057	09/01/1998	Smart et al.	
	BN	5,843,114	12/01/1998	Jang	
	BO	5,879,326	03/09/1999	Allen et al.	
	BP	6,050,988	04/18/2000	Zuck	

Examiner Signature		Date Considered	

PTO/SB/08A (10-01)
Approved for use through 10/31/2002.OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 4

Complete if Known	
Application Number	10/010723
Filing Date	December 6, 2001
First Named Inventor	Mark G. Allen
Art Unit	3763
Examiner Name	Thompson, Kathryn L.
Attorney Docket Number	BVTP-P04-506

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	BQ	EP 0497620	05/08/1992	Carnegie-Mellon University		
	BR	EP 0 652 600	5/1995			
	BS	JP 7132119	05/23/1995	Nikon Corp.		
	BT	JP 7196314	08/01/1995	Maruo Calcium Co., Ltd.		
	BU	WO 93/17754	09/16/1993	Elan Medical		
	BV	WO 96/37256	11/28/1996	Godshall		
	BW	WO 96/40365	12/1996			
	BX	WO 96/41236	12/19/1996	Regents of the University of CA		
	BY	WO 97/07734	03/06/1997	Spectrx, Inc.		
	BZ	WO 98/00193	01/08/1998	Altea Technologies		
	CA	WO 98/00194	01/08/1998	Sontra Medical		
	CB	WO 98/28037	07/02/1998	Alza Corporation		
	*CC	WO 00/48669	08/24/2000	Biovalve Technologies		
	*CD	WO 00/74763	12/14/2000	Georgia Tech Research		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

[1] Applicant's unique citation designation number (optional). [2] See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	*CE	Abrams, S.B. Versatile biosensor is compact and cheap. Biophotonics International 32-34 (Jan/FEb 1998).	
	CF	Amsden, B.G. and Goosen, M.F.A. Transdermal Delivery of Peptide and Protein Drugs: an Overview. AIChE J. 41, 1972-1977 (Aug. 1995).	
	CG	Brumlik, C.J. and Martin, C.R. Template Synthesis of Metal Microtubules. J. Am. Chem. Soc. 113, 3174-3175 (1991).	
	*CH	Chun, K. et al. Fabrication of Array of Hollow Microcapillaries Used for Injection of Genetic Materials into Animal/Plant Cells. Jpn. J. Appl. Phys. 38, 279-281 (1999).	
	*CI	Clarke, M.S.F. and McNeil, P.L. Syringe loading introduces macromolecules into living mammalian cell cytosol. J. Cell. Sci. 102, 533-541 (1992).	
	CJ	Despont, M. et al. High-Aspect-Ratio, Ultrathick, Negative-Tone Near-UV Photoresist for Mems Applications. IEEE 0-7803-3744-1/97 (1997).	
	CK	Edell, D.J. et al. Factors Influencing the Biocompatibility of Insertable Silicon Microshafts in Cerebral Cortex. IEEE Transactions on Biomedical Engineering 39, 635-643 (1992).	

Examiner Signature		Date Considered	

PTO/SB/08A (10-01)
Approved for use through 10/31/2002.OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	3	of	4

Complete if Known	
Application Number	10/010723
Filing Date	December 6, 2001
First Named Inventor	Mark G. Allen
Art Unit	3763
Examiner Name	Thompson, Kathryn L.
Attorney Docket Number	BVTP-P04-506

	*CL	Eleventh Annual International Workshop on Micro Electro Mechanical Systems, Heidelberg, Germany (25-29 Jan. 1998). IEEE Catalog No. 98CH36176	
	CM	Frazier, A.B. and Allen, M.G. Metallic Microstructures Fabricated Using Photosensitive Polymide Electroplating Molds. J. Microelectromechanical Systems 2, 87-94 (June 1993).	
	CN	Frazier, A.B. et al. Two Dimensional Metallic Microelectrode Arrays for Extracellular Stimulation and Recording of Neurons. IEEE 0-7803-0957 pp. 195-200 (Feb. 1993).	
	CO	Haga et al. Transdermal Iontophoretic delivery of insulin using a photoetched microdevice. J. Controlled Release 43, 139-149 (1997).	
	CP	Hashmi, S. et al. Genetic Transformation of Nematodes Using Arrays of Micromechanical Piercing Structures. BioTechniques 19, 766-770 (Nov. 1995).	
	CQ	Henry et al. Microfabricated Microneedles: A Novel Method to Increase Transdermal Drug Delivery. J. Pharm. Sci. 87, 922-925 (1998).	
	CR	Henry, S. et al. Micromachined Needles: A Novel Approach to Transdermal Drug Delivery. J. Pharm. Sci. 87, 922-925 (Aug. 1998).	
	CS	Hoffert, S.P. Transcutaneous Methods Get Under the Skin. The Scientist 12, no. 16 (17 Aug. 1998).	
	*CT	Infiltrator Intramural Drug Delivery: A New Generation of Drug Delivery Catheters from InterVentional Technologies, Inc., San Diego, CA (1997).	
	CU	Jaeger, R.C. Introduction to Microelectronic Fabrication in the Addison-Wesley Modular Series on Solid State Devices, G.W. Neudeck and R.F. Pierret, eds. Vol. 5, Addison-Wesley Publishing Co., Inc. (May 1993).	
	CV	Jansen, H. et al. The Black Silicon Method IV: The Fabrication of Three-Dimensional Structures in Silicon with High Aspect Ratios for Scanning Probe Microscopy and Other Applications. MESA Res. Int, University of Twente, The Nethlerlands.	
	CW	Laermer, F. et al. Bosch Deep Silicon Etching: Improving Uniformity and Etch Rate for Advanced MEMS Application. IEEE Catalog No. 99CH36291C, ISBN: 0-7803-5194-0 from the Twelfth IEEE International Conference on Micro Electro Mechanical Systems, Orlando FL, (17-21 Jan. 1999).	
	CX	Langer, R. Drug delivery and targeting. Nature 392 Supp, 5-10 (30 April 1998).	
	CY	Lehmann, V. Porous Silicon – A New Material for MEMS. IEEE ISBN: 0-7803-2985-6/96 (1996).	
	CZ	Lin, L. et al. Silicon Processed Microneedles. The 7th International Conference on Solid-State Sensors and Actuators (1993).	
	DA	Martin, C.R. et al. Template Synthesis of Organic Microtubules. J. Am. Chem. Soc. 112, 8976-8977 (1990).	

Examiner Signature		Date Considered	

PTO/SB/08A (10-01)
Approved for use through 10/31/2002.OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 4 of 4

Complete if Known	
Application Number	10/010723
Filing Date	December 6, 2001
First Named Inventor	Mark G. Allen
Art Unit	3763
Examiner Name	Thompson, Kathryn L.
Attorney Docket Number	BVTP-P04-506

	DB	Najafi, K. and Hetke, J.F. Strength Characterization of Silicon Microprobes in Neurophysiological Tissues. IEEE Transactions on Biomedical Engineering 37, 474-481 (May 1990).	
	DC	101 Uses for Tiny Tubules. Science 247 (23 March 1990).	
	DD	Percutaneous Absorption, R.L. Bronaugh and H.I. Maibach, eds. Marcel Dekker, Inc., New York (1989).	
	DE	Prausnitz, M.R. Reversible Skin Permeabilization for Transdermal Delivery of Macromolecules. Critical Reviews in Therapeutic Drug Carrier Systems 14, 455-483 (1997).	
	DF	Proceedings of the IEEE Micro Electro Mechanical Systems Conference 1987-1998; Rai-Choudhury, ed., Handbook of Microlithography, Micromaching & Microfabrication (SPIE Optical Engineering Press, Bellingham, WA 1997.	
	DG	Quan, M. Plasma etch yields microneedle arrays. Electronic Eng. Times, p.63 (13 July 1996).	
	*DH	Reiss, S.M. Glucose- and Blood-Monitoring Systems Vie for Top Spot. Biophotonics International p. 43-46 (May/June 1997).	
	DI	Runyan, W.R. and Bean, K.E. Semiconductor Integrated Circuit Processing Technology, Addison-Wesley Publishing Co. (1990).	
	DJ	Schift, H. et al. Fabrication of replicated high precision insert elements for micro-optical bench arrangements. SPIE Vol. 3513, p.122-134 from SPIE Conference on Microelectronic Structures and MEMS for Optical Processing IV, Santa Clara (Sept. 1998).	
	DK	Single-crystal whiskers. Biophotonics Int'l, p. 64 (Nov./Dec. 1996).	
	DL	Talbot, N.H. and Pisano, A.P. Polymolding: Two Wafer Polysilicon Micromolding of Closed-Flow Passages for Microneedles and Microfluidic Devices. Solid-State Sensor and Actuator Workshop, Hilton Head Island, SC (8-11 June 1998).	
	DM	Transdermal Drug Delivery, J. Hadgraft and R.H. Guy, eds. Marcel Dekker, Inc., New York (1989).	
	DN	Trimmer, W. et al. Injection of DNA into Plant and Animal Tissues with Micromechanical Piercing Structures. IEEE Catalog No. 95CH35754, ISBN: 0-7803-2503-6 from Micro Electro Mechanical Systems, Amsterdam p. 111-115 (1995).	
	DO	Weber, L. et al. Micro molding – a powerful tool for the large scale production of precise microstructures. SPIE No. 0-8194-2277-0/96, Vol. 2879, p.156-167 (1996).	
	DP	Zuska, P. Microtechnology Opens Doors to the Universe of Small Space. MD&DI (1997).	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	